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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/667,188
Filing Date: September 21, 2000
Appellant(s): ANDERSEN ET AL.

Thomas E. Holsten
David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2/7/2005.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

In particular, Appellants brief identifies the related decision by the Board in *In re Fisher* (U.S. Application No. 09/619,643, B.P.A. I. Appeal No. 2002-2046, Fed. Cir. Case No. 04-1465).

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-2 and 11-15 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

GenBank Accession Number BE428765 (July 26, 2000)

GenBank Accession Number AI861201 (July 19, 1999)

SIGMA Chemical Catalog, 1993, product O3628

SIGMA Chemical Catalog, 1993, product O4378

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claim Rejections - 35 USC § 101

Claims 1-2 and 11-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any polynucleotide. The specification discloses many potential uses for the polynucleotide including identifying promoters involved in gene regulation (page 38, lines 4- 6), determining whether a plant contains a mutation (page 38, lines 19-20), and acting as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function (page 15, lines 20-24). These are non-specific uses that are applicable to polynucleotides in general and not particular or specific to the

polynucleotide claimed. Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polynucleotides such that another non-asserted utility would be well established for the compounds.

B. Claim Rejections - 35 USC § 112, first paragraph (Enablement)

Claims 1-2 and 11-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

C. Claim Rejections - 35 USC § 112, first paragraph (Written Description)

Claims 1-2 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid encoding a plant protein comprising SEQ ID NO: 1. SEQ ID NO: 1, per se meets the written description provisions of 35 USC 112, first paragraph. However, the specification only describes a nucleic acid that is not a full-length open reading frame, but an EST, which has the sequence of SEQ ID NO: 1. The nucleic acid sequence of SEQ ID NO: 1 appears to [encode] a fragment of a larger protein since it was isolated from a *Triticum aestivum* cDNA library. The specification has provided no teachings as to a function for a protein encoded by isolated SEQ ID NO: 1 and provides no description of the remainder of the coding sequence of which SEQ ID NO: 1 is a fragment. The structure of the full-length coding sequence is not taught by the specification yet the claims encompass such. There is no description of what type of protein SEQ ID NO: 1 might be encoding. Consequently, the specification does not support applicant's possession of a nucleic acid encoding a plant protein comprising a nucleic acid sequence of SEQ ID NO: 1 at the time of filing.

In addition, claims such as claims 1 and 11-13 in the recitation of " ***a*** nucleic acid sequence of SEQ ID NO: 1" (claims 1, 13) and "***a*** nucleic acid sequence selected from the group of SEQ ID NO: 1" (claims 11 , 12) encompass sequences of any magnitude and/or content that comprise at least a minimum of a two base pair sequence of SEQ ID NO: 1. The claims are directed to encompass gene sequences, and complements of sequences of SEQ ID NO: 1, corresponding sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth. An example of the large variable genus are the fragments of the following nucleic acid Genbank entries from a variety of organisms that are encompassed by the claims:

- A9402486 Homo sapiens, positions 377-396 align 100% with positions 8-27 of SEQ ID NO: 1,
- BQ603510 Sus scrofa (pig), positions 10-29 align 100% with positions 7-26 of SEQ ID NO: 1,
- DR37H4 Danio rerio (zebrafish), positions 4-22 align 100% with positions 139-157 of SEQ ID NO: 1,
- BX513761 Mus musculus (house mouse), positions 420-402 align 100% with positions 7-25,
- B17542512 Rattus norvegicus (Norway rat), positions 286-214 align 100% with positions 196-214 of SEQ ID NO: 1; and
- AW871780 Xenopus laevis (African clawed frog), positions 378-396 align 100% with positions 127-145 of SEQ ID NO: 1.

The above specific regions align 100% with regions of SEQ ID NO: 1, thereby "comprising **a** sequence of SEQ ID NO: 1" and "complete complements thereof". Therefore, as seen above the breadth of the claims is very large to which there is insufficient description in the specification. Claim 2 requires the plant protein to be a wheat protein, however the specification does not disclose the content of the sequence that differentiates between a wheat protein and a non-wheat protein.

Claims 13- 15 recite substantially purified nucleic acid molecules having between 95% and 100% sequence identity to SEQ NO: 1 or a complement thereof (claim 13), a substantially purified nucleic acid having between 99% and 100% sequence identity with SEQ ID NO: 1 (claim 14), and a substantially purified nucleic acid according to claim 15 wherein the nucleic

acid comprises a region having a single nucleotide polymorphism. The specification, however, does not disclose the content of this polymorphic region, thus claiming a function without structure. These claims read on a very broad and highly variable genus of nucleic acid molecules which includes variants, homologs, and mutants of SEQ ID NO: 1, with either retained or altered function.

Beyond providing the sequence data for SEQ ID NO: 1, however, the specification provides no teaching or guidance which correlates the sequence of SEQ ID NO: 1 to its function, which amino acids in the protein encoded by SEQ ID NO: 1 are critical to its function, or how to modify SEQ ID NO: 1 to obtain any specific homolog, mutant, or variant. It is not clear which positions with SEQ ID NO: 1 can be substituted or altered without resulting in a loss of the function of SEQ ID NO: 1. Therefore, the skilled artisan would be unable to determine whether or not a DNA molecule is functionally equivalent to SEQ ID NO: 1. The claims provide for a large genus of nucleic acids that include undisclosed genes, partial genomic sequences, mutants, variants, and homologs of SEQ ID NO: 1, however the single disclosed structural feature of SEQ ID NO: 1 does not provide for a substantial portion of the claimed genus.

While one of skill in the art could argue that the claimed genus of polynucleotides is adequately described since one can isolate these polynucleotides by sequence comparison using the polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone should not be used to determine a protein's function and that small amino acid changes can drastically change the function of a polypeptide. Bork (Genome Research, 10: 398-400; 2000) teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Van de Loo

et al. (PNAS 92; 6743-6747; 1995) teaches that polypeptides of approximately 67% homology to a desaturase from Arabidopsis were found to be hydroxylases once tested for activity. J. Seffernick et al. (J. Bacteriol. 183 (8), 2405-2410; 2001) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. ; (Science 282: 1315-1317; 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydroxylase and as few as six amino acid substitutions can transform a hydroxylase to a desaturase. The genus of polynucleotides comprised by the claim is a large variable genus, which can potentially encode proteins of diverse functions. The specification only discloses a single species of the genus, i.e. the polynucleotide of SEQ ID NO: 1, which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed with respect to claims 1, 2 and 11-15.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of a substantially purified nucleic acid molecule consisting of the sequence of SEQ ID NO: 1, and the complete complement thereof, the skilled artisan cannot

envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide a written description of the invention of claims 1, 2 and 11-15. This is a rejection based on a lack of WRITTEN DESCRPTION.

D. Claim Rejections - 35 USC § 102

(I) Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(a) as being anticipated by the GenBank accession number BE428765 (26-July-2000).

The GenBank accession number BE428765 is a mRNA from the wheat plant Triticum turgidum and comprises a nucleic acid sequence of SEQ ID NO: 1 (for example, nucleic acid positions 46-251 of SEQ ID NO: 1). The aligned sequence segment of positions 98-303 is 100% identical to SEQ ID NO: 1. A nucleic acid molecule or a fragment of nucleic acid positions 46-251 of SEQ ID NO: 1 would be a complete complement to the accession number positions 98-303, therefore the instant accession number anticipates the claimed nucleic acid. With respect to claim 15, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 13. Any sequence can potentially comprise a SNP and depends on what one is comparing it to. Therefore the GenBank accession number BE42765 anticipates claims 1, 2 and 11-15 as a nucleic acid molecule comprising of a nucleic acid sequence of SEQ ID NO: 1.

(II) Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by the GenBank accession number AI861202 (19-July-1999).

The GenBank accession number AI861202 is a mRNA from the plant Zea mays and comprises a nucleic acid sequence of SEQ ID NO: 1 (for example, nucleic acid positions 314-332 of SEQ ID NO: 1. The aligned sequence segment of positions 169-187 is 100% identical to SEQ ID NO: 1. A nucleic acid molecule or a fragment of nucleic acid positions 314-332 of SEQ ID NO: 1 would be a complete complement to the accession number nucleotide positions 169-187, therefore the instant accession number anticipates the claimed nucleic acid. With respects to claim 15, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 13. Any sequence can potentially comprise a SNP and

depends on what one is comparing it to. Therefore the GenBank accession number AI861202 anticipates claims 1, 2 and 11-15 as a nucleic acid molecule comprising or consisting of **a** nucleic acid sequence of SEQ ID NO: 1.

(III) Claims 1, 2 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by products O3628 and O4378 of the 1993 SIGMA Chemical Catalog.

In the 1993 Sigma Chemical Catalog product O3628 is a 7-mer oligonucleotide of poly dT nucleotides and product O4378 is a 4-mer oligonucleotide of poly dA nucleotides, both of which are 100% identical to a nucleic acid sequence of SEQ ID NO: 1. It is noted that these oligonucleotides are at least about 95%-100% (and 99%-100%) identical to poly T segments or their complementary respective poly A segments of the instantly claimed nucleic acids. They thus anticipate instant claims 1 and 11-14 via segments therein which are poly T segments or poly A segments present in the SEQ ID NO: 1 (nucleic acid positions 7-15 and 189-193 respectively). With respects to claim 15, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 13. Any sequence can potentially comprise a SNP and depends on what one is comparing it to. Therefore the O3628 and O4378 products anticipate claims 1, 2 and 11-15 as a nucleic acid molecule comprising or consisting of a nucleic acid sequence of SEQ ID NO: 1.

(11) Response to Argument

A. Claim Rejections - 35 USC § 101 (Utility)

The appeal brief filed February 7, 2005 traverses this rejection. Appellant's arguments have been fully considered but are not persuasive for the reasons that follow.

At pages 5-6 the brief traverses that the lack of utility analysis misstates the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" and applies case law in support for the doctrine of "practical utility" and the requirement for "identifiable benefit". These arguments are not specifically drawn to the rejection set forth previously or above, and are an allegation. They are found non-persuasive and are reasonably an introductory summary set forth by the brief. As a preliminary matter, the rejections in this application are made in order to comply with office policy regarding the utility guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.). So to the extent that any argument conflicts with the guidelines, it will necessarily be non-persuasive.

Appellants assert at page 3 and pages 7-8, that they have met the conditions of providing the public with an invention having substantial utility wherein specific benefit exists in currently available form. Appellants state that, in particular, the claimed nucleic acids can be used to identify a polymorphism in a population of wheat plants. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all wheat plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID

NO: 1. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 1 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic of a particular strain of wheat plant. Therefore, the nucleic acids of SEQ ID NO: 1 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As set forth in the MPEP (2107):

> On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
>
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
>
> (B) A method of treating an unspecified disease or condition;
>
> (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
>
> (D) A method of making a material that itself has no specific, substantial, and credible utility; and
>
> (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Each of these situations closely matches Appellant's disclosed uses. These uses do not define substantial utilities.

Further, MPEP 2107 states that:

> An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

However, in the present situation, the specification does not disclose a correlation between such polymorphisms and any conditions or traits.

Appellants assert that the use of the claimed nucleic acids to detect a polymorphism is analogous to the utilities associated with a microscope, i.e., the claimed nucleic acids may be used to locate and measure nucleic acid molecules in a sample, cell or organism. However, the use of a nucleic acid to detect a polymorphism is not considered to be analogous to the use of a microscope. The microscope can be used to immediately provide information. For instance, the microscope can be used to identify or distinguish between gram-positive and gram-negative bacteria. This use is well known and its benefits are immediately recognizable. The use of a nucleic acid to detect a polymorphism does not provide information of immediate benefit. If a researcher determines that a polymorphism is present, the researcher would not know what to do with this information since the specification has not disclosed a specific association between any particular polymorphisms and any particular traits. This situation is significantly distinct from a situation in which a nucleic acid is to be used to detect a previously disclosed polymorphism known to be associated with a specific trait. In such a situation, the nucleic acid would have a specific and substantial utility because the information obtained by detecting the polymorphism is specific and of immediate benefit. In contrast, the present invention requires the researcher to first identify a new polymorphism and then determine whether this polymorphism is associated with any particular trait or condition. The information gained by detecting an unknown and uncharacterized polymorphism is not specific and not of immediate benefit.

Appellants assert that the use of the claimed nucleic acid molecules to detect the presence or absence of a polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas. However, the gas chromatograph example set forth by Appellant is not analogous to the present disclosure. A gas chromatograph is a piece of equipment designed and built for a particular use. Such equipment is fully tested, evaluated and calibrated to ensure accurate results. Those skilled in the art know how to use the gas chromatograph to analyze both known and unknown samples. When a sample is unknown, the results may be compared to a standard or reference. However, Appellants have not tested, evaluated or calibrated the claimed nucleic acids for any particular use. Screening for the presence or absence of chlorine in a sample is not equivalent to screening for the presence or absence of an unknown polymorphism. Given that the composition and features of chlorine are well known in the art, the detection of chlorine in a sample has a known meaning to those in the art based upon prior research. In the example discussed in the brief, absent an association between the presence of chlorine and the destruction of a catalyst, the presence or absence of chlorine in a sample would not provide any useful information to the refinery manager. Likewise, the presence or absence of any of the claimed nucleic acids in a sample (or a polymorphism) has no meaning absent an association between the nucleic acid or polymorphism and some other property. Further experimentation is required to determine what that meaning or association might be.

Appellants assert that the specification teaches that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in microarrays as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or

mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific utility. As with the use of a nucleic acid to detect polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 1 or a protein encoded by SEQ ID NO: 1 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of a mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid. The use of the claimed nucleic acids to detect homologues in other plants and organisms such as alfalfa and barley, as argued at page 9 of the brief, is also not a substantial and specific utility. Since the functional activity of the presently claimed nucleic acids is unknown, and the functional activity of any putative homologues is unknown, the detection of such homologues does not provide an immediate benefit and serves only as a starting point for further research. In addition, the use of a nucleic acid in a microarray does not confer a patentable utility since all nucleic acids may be used in microarrays. Each of these asserted utilities are generic, rather than specific. Use of the claimed nucleic acids in the above manners would not be meaningful in the absence of information regarding the specific biological activity or significance of these nucleic acids.

Appellants assert that the claimed nucleic acids may be used to initiate a chromosome walk to identify, e.g., a promoter in the corresponding gene. However, the specification fails to demonstrate that the claimed nucleic acids could in fact be used to obtain any meaningful results from such a search. The specification does not define the structural or functional properties of any promoters associated with SEQ ID NO: 1. Even if such a promoter exists, there is no specific guidance provided in the specification for identifying the promoter. For instance, the specification does not disclose the location of the promoter, the distance between the promoter and the claimed nucleic acids, or the sequence of the promoter. Initiation of a chromosome walk at the corresponding chromosomal location is considered a non-specific utility because any EST would serve this purpose for isolating an uncharacterized promoter since any chromosomal location would be linked to some promoter. Additionally, since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one in the art that it has been isolated, there can be no "immediate benefit to the public" in using the claimed nucleic acid molecules in this manner. Appellants assert that the claimed nucleic acid molecules are particularly useful to identify markers and isolate promoters functional in anthers in *Triticum aestivum*, however any nucleic acid similarly isolated as the claimed nucleic acid might be used as such. The specification teaches no function or activity for the protein that SEQ ID NO: 1 might encode, nor teaches which "important genes" associated with plant growth, quality, and yield would be isolated by the claimed SEQ ID NO: 1, or what "important developmental, metabolic, and catabolic pathways" SEQ ID NO:1 may be a link to. Plant nucleic acids, in general, could be used to "isolate agronomically important genes associated with plant growth, quality, and yield" and could serve as "links in important

developmental, metabolic and catabolic pathways." However, the specification provides no specific, or substantial utility that takes advantage of the particular combination of nucleotides in the presently claimed nucleic acid molecule.

At page 10 of the brief, Appellants draw an analogy between golf clubs and nucleic acids. It is stated that "the golf club is generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs." Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* in support of their arguments. However, the cited decision was made with respect to a mechanical device and not with respect to a molecular compound to be used as a laboratory reagent or a research tool. The facts of the cited case do not correspond to those of the instant application since the utilities associated with a golf club do not compare to the utilities associated with a nucleic acid. While one knows how to use a golf club in a specific manner, one does not know how to use the claimed nucleic acids in a specific manner. The specification does not teach the skilled artisan how to use the claimed nucleic acids for a specific purpose (such as to "hit the ball in a manner that is distinct from other clubs"). Rather, the specification invites the skilled artisan to perform experimentation in order to determine how to use the claimed nucleic acids for a specific purpose.

At page 12, the brief traverses the rejection by arguing that there is no question that the public has recognized the benefits provided by the claimed subject matter. It is asserted that a multi-million dollar industry has been established with ESTs. However, the evidence provided by Appellants shows that a multimillion dollar industry has arisen surrounding buying and selling EST databases and clones. Appellants have not established the market value of the presently claimed ESTs. Further, it is noted that simply because a product, such as an EST

sequence database or a clone library, is bought and sold does not mean that the product has patentable utility.

With regard to Appellant's arguments concerning credibility, the credibility of the asserted uses has not been challenged. It is acknowledged that detection of a polymorphism, for example, constitutes a credible utility. Appellant is reminded that in order to meet the requirements of 35 U.S.C. 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of a well established utility, which would presume that the utility was credible). In the instant situation, the claims remain rejected because the specification does not disclose at least one use that is specific and substantial and no convincing evidence has been provided to show that the disclosed EST, for which only a nucleotide sequence and source have been provided, has a well established utility. Accordingly, the lack of utility remains because there is no well established utility or a specific and substantial utility for the claimed invention.

As set forth above, the rejection is based on the finding that Appellants have not disclosed a substantial and specific or well-established utility for the claimed invention. The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966) wherein the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that :

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion."

In the present situation, Appellants have not arrived at a "successful conclusion" as to the actual functional role or significance of the claimed nucleic acids. Without such information, the claimed nucleic acids can only be used as a starting point for conducting further experiments to arrive at a "successful conclusion."

B. Claim Rejections - 35 USC § 112, first paragraph (Enablement)

The brief at page 14 states that this rejection is erroneous and has been overcome by the arguments stated above regarding utility. However, for the reasons set forth above, it is maintained that the uses asserted for the claimed invention are an object of study and are not specific, nor substantial. The specification cannot enable or teach one how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. Because there is no utility for the claimed invention for the reasons set forth above, it is maintained that the specification has not enabled the claimed invention.

C. Claim Rejections - 35 USC § 112, first paragraph (Written Description)

The brief traverses the written description rejection. It is argued that the specification demonstrates that Appellant was in possession of the claimed genus of nucleic acid molecules. It is further asserted that the fact that the claims are joined with additional sequences, or complements of the recited sequence or nucleic aid molecules that share a claimed identity with the recited sequence does not mean that Appellant was any less in possession of the claimed nucleic acid molecules. This argument was thoroughly reviewed but was not found persuasive. The rejection is based on the fact that the claims include full length genomic sequences comprising the recited SEQ ID NO: 1. With regard to claim 2, the specification provides no description as to attributes which would make a sequence as claimed in claim 1, encode a wheat

protein, as opposed to any protein in general. With regard to claims 13-15, the claims further encompass sequences having 95% to less than 100% identity with SEQ ID NO: 1 and sequences comprising these variant sequences. Thereby, the claims encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 1 which are not adequately described in the present specification.

Appellants state that the application describes more than just the nucleotide sequence of SEQ ID NO: 1. It is asserted that the specification describes vectors comprising the claimed nucleic acid molecules, the addition of other nucleotides or detectable labels, fusion peptides, as well as sequences having particular sequence identity to claimed nucleic acid molecules. Appellants cite Enzo Biochem (Fed. Cir. 2002) as stating that the written inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, mixtures of those sequences are also described to one of skill in the art."

These arguments have been fully considered but are not persuasive. The genus of nucleic acids encompassed by the claims is extremely broad and is not limited to vectors comprising the nucleic acids or to nucleic acids comprising a label. The claims further encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 1. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, SNPs, polymorphic sequences, promoter sequences and exogenous sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids. As discussed in the rejection, the court in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), held that "An adequate written

description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". While Appellants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. In the present situation, Appellants have provided only a disclosure of a wish to obtain homologues, mutant, allelic, and splice variants of SEQ ID NO: 1. The specification does not disclose any specific mutant, allelic, or splice variants or homologues of SEQ ID NO: 1. Further, the functional activity of such variants is not disclosed. Accordingly, the specification has not disclosed a representative number of nucleic acid molecules within the claimed genus.

Appellants assert that they have disclosed the common structural features of the claimed nucleic acids, i.e., SEQ ID NO: 1. However, the claims are not limited to nucleic acids which share this common structural feature. Rather, the claims encompass nucleic acids having 95-99.9% identity with SEQ ID NO: 1. Thereby, the claimed genus of nucleic acids do not share the same common structural feature of containing the sequence of SEQ ID NO: 1. Appellants have not disclosed what specific sequence information must be shared by the claimed genus of nucleic acid molecules in order to ascertain which nucleic acids share a common structural feature. The genus of molecules having 95-99.9% identity with SEQ ID NO: 1 includes individual species of nucleic acids which may vary from SEQ ID NO: 1 at any given nucleotide position within SEQ ID NO: 1. When the individual species within the genus are compared to one another, together this genus comprises nucleic acids which vary at each and every nucleotide position within SEQ ID NO: 1. Accordingly, the genus of nucleic acids are not considered to share a common

structural feature – i.e., there is no specific structural property that is common to all members of the claimed genus if each of the individual nucleotides may be varied. Further, the claims do not recite a functional requirement for any of the claimed nucleic acids and thereby encompass nucleic acids having distinct functional properties.

At page 18, Appellants state that "closely related nucleic acid molecules falling within the scope of the invention are readily identifiable – they either contain the nucleic acid sequence of SEQ ID NO: 1 or share a claimed identity with SEQ ID NO: 1, or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's analysis, claims 1-2 and 11-15 are supported by an adequate written description." These arguments have been fully considered but are not found persuasive. It is noted that the criteria for meeting the Written Description requirement is not limited to providing a means for distinguishing between molecules which fall within the claimed genus and molecules which fall outside the claimed genus. Rather, the Written Description requirement is met by providing a showing that Appellants were, at the time the application was filed, in possession of the claimed invention. Providing a statement that the invention covers nucleic acid having 95-99.9% identity with SEQ ID NO: 1 is not equivalent to disclosing specific nucleic acids which fall within the claimed genus of nucleic acids. The specification does not disclose a single molecule within the genus of nucleic acids having 95-99.9% identity with SEQ ID NO: 1. The specification does not describe the location or identity of nucleotides which may be varied within SEQ ID NO: 1, and does not describe the functional activity or other biological role associated with such variants. The specification also does not

disclose any specific variants of SEQ ID NO: 1 which have a functional activity or biological role distinct from that of SEQ ID NO: 1. Modification of a nucleic acid sequence by 1 to 5% can significantly alter the functional activity of the nucleic acid and the protein encoded thereby. The genus of nucleic acids claimed is large and variable, and potentially includes nucleic acids encoding for proteins having diverse biological functions. The specification discloses only one member of this genus, i.e., SEQ ID NO: 1. This is not sufficient to place one of skill in the art in possession of a representative number of molecules having the varied attributes and features of species within the claimed genus. Accordingly, it is maintained that the written description requirements have not been adequately met for the broadly claimed genus of homologues, splice, mutant and polymorphic variants of SEQ ID NO:1.

D. Claim Rejections - 35 USC § 102

The brief traverses the 102 rejections to Genbank Accession numbers BE428765 and AI861202. Appellants assert that Genbank Accession numbers BE428765 and AI861202 do not disclose SEQ ID NO: 1 or a complete complement or variation thereof with the pending claims and cannot anticipate the claimed invention. It is noted that the rejections set forth under 35 USC 102 did not assert that either Genbank Accession number taught SEQ ID NO: 1, the complete complement of SEQ ID NO: 1, or a sequence with the disclosed % identity over the full length of SEQ ID NO: 1. As set forth above the claims recite "a" sequence and "a" complement. Appellants assert that "the Examiner has applied an untenable interpretation of the pending claim to cover small fragment of the specifically claimed nucleic acid molecules, i.e. molecules as short as one dimer or two nucleotides...". Appellants assert that this is not correct. These arguments have been thoroughly reviewed but were found unpersuasive. The examiner

has construed the claims broadly. The specification has not defined the recitation in the claims to be limited to "the" sequence of SEQ ID NO:1. The recitation of "a" sequence or "a" complement has been broadly interpreted. The claims have thus been broadly construed to encompass sequences comprising sequences within SEQ ID NO: 1, complete complements of such, as sell as sequences with the recited % identity to sequences within SEQ ID NO: 1. With regard to claim 15, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 13. Any sequence can potentially comprise a SNP and depends on what one is comparing it to.

Appellants assert that claims 1-2 and 11-15 have been erroneously rejected under 35 USC 102(b) over products O3628 and O4378 from Sigma Chemical Catalog. Appellants state that Sigma Catalog does not disclose SEQ ID NO: 1 or a complete complement thereof or variation thereof and cannot anticipate the claimed invention. It is noted that the rejections set forth under 35 USC 102(b) did not assert that either product O3628 or O4378 taught SEQ ID NO: 1, the complete complement of SEQ ID NO: 1, or a sequence with the disclosed % identity over the full length of SEQ ID NO: 1. As set forth above the claims recite "a" sequence and "a" complement. Appellants assert that "the Examiner has applied an untenable interpretation of the pending claim to cover small fragment of the specifically claimed nucleic acid molecules, i.e. molecules as short as one dimer or two nucleotides...". Appellants assert that this is not correct. Appellants assert that "It is axiomatic that claims are to be read in light of the specification" and cites *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). Appellants further state that the examiner has not read the claims in light of the specification and that no where does it state that a nucleic acid sequence or complement or variant be as short as two nucleotides. This

argument has been thoroughly reviewed but was found unpersuasive. It is noted that the decision in *In re Vogel* was with respect to construction of specification and claims with regard to Double Patenting, and not to rejections applied under 35 USC 102. Further, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The specification does not specifically or expressly limit the claimed nucleic acids to exclude any particular length. Accordingly, the examiner has construed the claims broadly. The specification has not defined the recitation in the claims to be limited to "the" sequence of SEQ ID NO:1. The recitation of "a" sequence or "a" complement has been broadly interpreted. The claims have thus been broadly construed to encompass sequences comprising sequences within SEQ ID NO: 1, complete complements of such, as sell as sequences with the recited % identity to sequences within SEQ ID NO: 1. With regard to claim 15, the recitation of "comprises a region having a single nucleotide polymorphism [SNP]" does not structurally limit claim 13. Any sequence can potentially comprise a SNP and depends on what one is comparing it to.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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